Jeremy C. Johnson, Bar #025203
JONES, SKELTON & HOCHULI, P.L.C.
40 North Central Avenue
Suite 2700
Phoenix, Arizona 85004
Telephone: (602) 263-4453
Facsimile: (602) 200-7868
jjohnson@jshfirm.com

Counsel for Petitioner
SmileDirectClub, Inc.

UNITED STATES DISTRICT COURT DISTRICT OF ARIZONA

SmileDirectClub, Inc.)
Petitioner,	
v.	CASE NO.
Align Technology, Inc.	Memorandum In Support OfPetitioner's Motion to Compel
Respondent.) reductier's Motion to Comper)

I. <u>INTRODUCTION</u>

Petitioner SmileDirectClub, Inc. ("Petitioner" or "SDC") seeks to enforce a Rule 45 subpoena *duces tecum* served on Respondent, Align Technology, Inc. ("Align") that seeks documents relevant to the plaintiffs' claims and SDC's defenses in a nationwide class action lawsuit pending in the United State District Court for the Middle District of Tennessee, *Ciccio v. SmileDirectClub, LLC, et al.*, Case No. 3:19-845 (Trauger, J.). As set forth below, the subpoena seeks documents that go to the heart of SDC's defenses to claims asserted against it by a group of disgruntled orthodontists, many of whom are providers of Invisalign® brand clear teeth aligners, manufactured and sold by Respondent Align, who claim that, but for allegedly "false" statements made by SDC about its competing brand of clear aligners, these orthodontists would have recruited new patients and made more money selling their competing products, including products manufactured by Align.

On February 24, 2021, in view of the contractual relationship between the plaintiff

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1 orthodontists and Align, SDC issued a third-party subpoena to Align containing fifteen document requests. (Exhibit A.)¹ On March 18, 2021, Align's counsel responded to the subpoena, but instead of producing any documents, they asserted a collection of rote objections. (Exhibit B.) After SDC experienced some difficulty arranging a date to see if the parties could agree to a compromise (Exhibit D, an hour-long telephonic meet-andconfer conference that was held on Friday, April 9, 2021. (See Declaration of David A. Rammelt ("Rammelt Decl.") at ¶ 8). During that call, Align's counsel was unwilling to produce an documents. (Rammelt Decl., ¶ 9). Although Align's counsel argued that the 9 requests are "overbroad and subject[] Align to unreasonable and undue annoyance, 10 oppression, burden, and expense," there was no support given for this position. Specifically, counsel for Align admitted that they had conducted no searches, had no idea of the volume or burden associated with responding to any of the requests, and frankly did 13 not know if they even had any documents, though he admitted that "I am sure we do" have some documents. (Rammelt Decl., ¶ 10). Accordingly, SDC brings the instant motion to enforce the subpoena at issue.

II. THE LEGAL STANDARD

The Federal Rules of Civil Procedure allow parties to "obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." FED. R. CIV. P. 26(b).

"[T]he test for 'relevance,' in the context of a Rule 45 subpoena to a non-party, is no different than the test under Rules 26 and 34." Aquastar Pool Prods. Inc. v. Paramount Pool & Spa Sys., No. CV-19-00257-PHX-DWL, 2019 U.S. Dist. LEXIS 8273, at *5 (D. Ariz. Jan. 16, 2019) (citing Transcor, Inc. v. Furney Charters, Inc., 212 F.R.D. 588, 591 (D. Kan. 2003) ("It is well settled . . . that the scope of discovery under a subpoena is the same as the scope of discovery under Rule 26(b) and Rule 34. Thus, the court must examine whether a request contained in a subpoena duces tecum is overly broad or seeking irrelevant information under the same standards set forth in Rule 26(b) and as applied to

¹ The date on the subpoena is "02/24/2020," which is a typographical error.

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1 Rule 34 requests for production.") (alteration in original); FED. R. CIV. P. 45, advisory committee notes to 1970 amendment ("[T]he scope of discovery is the same as that applicable to Rule 34 and the other discovery rules.")).

"Relevancy, for purposes of discovery, is defined broadly" Gonzales v. Google, Inc., 234 F.R.D. 674, 679-80 (N.D. Cal. 2006). Indeed, as this Court observed in Aquastar Pool Products, "some courts have suggested that relevance should be construed even more broadly than usual when, as here, the judge overseeing the litigation over the subpoena isn't handling the underlying case." Aquastar Pool Prods., 2019 U.S. Dist. LEXIS 8273, at *5-6 (emphasis added) (citing *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 10 1024 (Fed. Cir. 1986) ("[C]ourts with jurisdiction over ancillary or discovery matters should be cautious in determining what is relevant evidence to the main action . . . because of their unfamiliarity with the main action. Where there is doubt over relevance, . . . the court should be permissive.") (alterations in original) (emphasis added)).

In the case of a subpoena served on a third party, consideration is given to the burden and expense that may be required of a non-party. "The proper way to afford this special consideration is to 'weigh the burden to the subpoenaed party against the value of the 17 information to the serving party. Generally, this requires consideration of relevance, the 18 need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed." Aquastar Pool Prods., 2019 U.S. Dist. LEXIS 8273, at *6-7 (citing Soto v. Castlerock Farming & Transport, Inc., 282 F.R.D. 492, 504 (E.D. Cal. 2012)); see also Wood v. Vista Manor Nursing Ctr. Life Generations Healthcare, Inc., et al., No. C-06-01682-JW (PVT), 2007 U.S. Dist. Lexis 22643, at *8-9 (N.D. Cal. Mar. 16, 2007).

A nonparty may be compelled to produce documents. FED. R. CIV. P. 34(c) (citing FED. R. CIV. P. 45). The nonparty may object to the serving party's request but, "[a]t any time, on notice to the [nonparty], the serving party may move the court for the district where compliance is required for an order compelling production or inspection." FED. R.

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CIV. P. 45(d)(2)(B)(i).² The serving party must show the requested documents are relevant to its claims or defenses and proportional to the needs of the case. FED. R. CIV. P. 26(b)(1). Reasonably accessible electronically-stored documents must be produced, while non-reasonably accessible electronically-stored information need not be produced immediately, but may need to be produced later if good cause is shown. *See* Adv. Comm. Note to 2006 Amendment to Fed. R. Civ. P. 26(b)(2).

An objecting nonparty must show the information requested is not reasonably accessible due to undue burden or cost. FED. R. CIV. P. 26(b)(2)(B); *see also* Fed. R. Civ. P. 45(d)(1), (d)(3)(A)(iv); *Tyler v. City of San Diego*, No. 14-cv-01179-GPC-JLB, 2015 U.S. Dist. LEXIS 56309, at *4 (S.D. Cal. Apr. 29, 2015) (a party must make "particular and specific demonstration[s] of fact" that "provide sufficient detail" as to show undue burden) (internal citations omitted). Even if this burden is met, the court may nonetheless order discovery if the requesting party shows good cause within the limitations of Rule 26(b)(2)(C).

III. ARGUMENT

A. The Align Documents Sought by SDC are "Relevant"

1. Background: The Underlying Lawsuit & Align's Involvement

In order to understand the relevance of SDC's document requests, some background about its business and Align's involvement is helpful. Founded in 2014, SmileDirectClub is a pioneer, and a disrupter, in the field of traditional orthodontia by being the first to offer doctor-directed, remote clear aligner treatment to address mild to moderate malocclusions. SDC uses its innovative teledentistry platform that relies on a network of more than 250 affiliated state-licensed dentists and orthodontists. SDC's clear aligner treatment requires no in-person office visit—which is especially important in rural and Native American communities because many households in the United States do not have a single

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² The subpoena indicated that the documents could be served at SDC's counsel's office in Wilmington, DE—or wherever Align chose, since any production is likely to be electronic. Align's world headquarters and principal place of business is 410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85281 (https://www.aligntech.com/contact_us). Accordingly, this is the appropriate forum to bring this motion.

orthodontist in their counties—and is priced at about 1/3 of the cost of Align's clear aligners. The cost differential alone allows SDC to increase consumer access to care. Align, on the other hand, in addition to being more expensive, requires an in-person office visit, which makes their services unavailable to many Americans.

For several years, Align itself manufactured millions of plastic clear aligners sold by SDC, pursuant to an exclusive third-party supply agreement ("Supply Agreement"). Clear aligners are classified by the U.S. Food & Drug Administration ("FDA") as a Class II medical device and as such, require clearance in accordance with Section 510(k) of the Food, Drug & Cosmetic Act. During the period that SDC was a re-packager and re-labeler of aligners manufactured by Align, SDC relied upon Align's 510(k) clearance as permitted by the FDA and the Supply Agreement. Align was only too happy to have SDC sell Align's aligners through SDC's doctor-directed remote treatment, without the need for an office visit. Moreover, Align was also the largest investor in SDC between 2016 and 2019, owning a 19% equity interest in the company.

In addition, Align's Chief Executive Officer, Joe Hogan, sat on SDC's Board of Directors for years until 2019. Mr. Hogan's attitude regarding SDC's business model was directly correlated to whether he was selling Align's clear aligners to SDC; he has been both complimentary and critical in turns. For example, during a public August 2016 "Ask The Expert" chat with Mr. Hogan, he extolled the virtues and safety of SDC's model:

I took it upon myself to go and meet the owners and founders of SmileDirectClub in March of this year in Tennessee and sat down and talked to the team there, and I was very impressed in the sense of their experience in what they would call direct to consumer models. I would say this is not a direct to consumer model, this is a doctor directed model, and I am not being cute here. I'll walk you through the work flow that shows you that it is doctor directed and the decision making process is through doctors.

* * * *

Their model is very simple and it's simple in the sense that its goal is to stay out of a doctor's office and to address very easy interior movements of teeth. There's no molar movements in the protocols that they use for these kinds of things.

* * * *

They have regulatory with approval in 49 of 50 states, which means they have met with a number of attorney generals around the country in a sense of this business model and having discussions of why this business model fits what commerce clauses would be in those specific states. SmileDirectClub business model, again, is low cost clear liners shipped directly to a consumer home for simple teeth straightening. But again I want to emphasize it is done remotely by a doctor, no office visits, but it's a remote kind of a process.

(Uncertified transcript of call attached as **Exhibit E** at 1, 3 (emphasis added).)³

But since March 2019, Align and Mr. Hogan have done a 180-degree change in position and been vocally critical of SDC's platform, claiming that the lack of an office visit, among other things, made SDC's model "unsafe" and in violation of the standard of care in the dental industry. For example, in a "Fact Sheet" distributed by Align sometime in 2019 or 2020, Align now argued that an in-person examination was required and that the failure to do so was not professional:

Align believes that, in certain contexts, Teledentistry is a valuable tool for dentists, but it does not replace the need for a responsible professional. A patient, on their own, cannot determine if they are a good candidate for clear aligner treatment. Further, without an inperson examination, a dentist will have limited information on which to base a diagnosis or treatment plan for them.

Intraoral scans and photographs are not a complete record... Prior to the start of orthodontic treatment, a dentist should conduct an inperson, physical examination of the patient and, if indicated by that examination, review or order radiographs to confirm that they are a good candidate for treatment. This should be required by law.

(Exhibit F (emphasis added).)

Mr. Hogan's changing story can be traced to a AAA arbitration SDC brought and won against Align in March 2019 because of Align's breach of certain restrictive covenants in its operating agreements. This arbitration resulted in the arbitrator issuing an order requiring Align to sell back its equity in SDC at a value far below its then fair market value, and an injunction requiring Align to close all of its competing retail stores. The arbitrator also found that Align had received "mountains of confidential information" from SDC and

³ A recording of the full conversation is available online at https://s3.amazonaws.com/storagy-gati-production-us/podcasts/video/ate_080516.mp4.

ruled Align was permanently precluded from using same. Although Mr. Hogan and Align had no concerns whatsoever with SDC's remote teledentistry business model when SDC was purchasing and reselling clear aligners from Align, the arbitration loss prompted Mr. Hogan to change his story:

Since April 2018 Align has been engaged in an arbitration proceeding with the SDC Entities stemming from the claim that our Invisalign retail stores violate non-compete provisions applicable to the members of SDC Financial LLC, including Align . . . Throughout this process we have maintained that we have acted in good faith and integrity with regards to the SDC Entities and our contractual obligations. And we believe that what makes Invisalign Stores and every part of the Invisalign experience substantially different from SDC scan shops is our focus on a doctor's office for treatment. While we are disappointed by the arbitrator's decision, it has no bearing on our long-held strategy of educating millions of consumers worldwide on the benefits of a having better smile and connecting them directly with Invisalign providers. We'll continue to raise consumer awareness and drive patients to doctor's offices for great outcomes and great treatment experiences,"

(**Exhibit G** (emphasis added).)

These attacks were picked up and repeated by dental trade organizations. On April 25, 2019—tellingly, approximately one month after Align lost the arbitration against SDC⁴—the American Dental Association ("ADA") filed a Citizen's Petition with the FDA accusing SDC of, among other things, illegally selling aligners without FDA 510(k) clearance. (**Exhibit H**.) In addition to these claims, the ADA emphasized the lack of an in-person office visit and examination as falling below the "standard of care" in the dental industry, just as Mr. Hogan had accused in his press release. Less than six weeks after the Petition was filed by the ADA, it was rejected by the FDA on May 30, 2019. (**Exhibit I**.)

Upon information and belief, Align had communications and/or meetings with the ADA. Another entrenched dental trade organization, the American Association of Orthodontists ("AAO") has also attacked SDC's business model through a variety of tactics. It is beyond dispute that Align has had meetings and other communications with the AAO about SDC. For example, in a May 2019 presentation to the AAO Board about

⁴ See Align Press Release dated March 5, 2019, attached as Ex. G.

its activities, the AAO specifically noted that it was having meetings with Align: "Held several meetings with Align to improve relationships." (**Exhibit J** at 42.)

2. SDC's Narrowly-Tailored Requests are Directly Relevant to the Allegations in the Underlying Class Action Lawsuit

The underlying class action giving rise to this motion was filed on September 24, 2019, in the Middle District of Tennessee. (*See* current Amended Complaint, **Exhibit K**.) Three orthodontists – two of whom are "certified" Invisalign® providers (*see* Kapit Admission No. 57, **Exhibit L**; Ciccio Admission No. 57, **Exhibit M**) – allege that SDC made false statements about its treatment model and that these orthodontists were damaged as a result. This means that they (and every other orthodontist who is also an Invisalign® provider and potentially part of this nationwide class action) are closely aligned with Respondent. Front and center to their complaint are allegations that largely repeat the charges leveled by Align, the ADA, and the AAO, as discussed aboove.

Although the entire underlying Amended Complaint is attached (**Exhibit K**), a summary of some of the key allegations are necessary to view SDC's discovery requests, and hence relevance, in context. Among other things, the Invisalign® orthodontists allege:

SmileDirect is a company under siege. It is currently subject to a barrage of litigation and customer complaints that challenge its business model and set forth substantiated allegations that SmileDirect is operating illegally in violation of provisions of the federal Food, Drug, and Cosmetic Act (the "FD&C Act"). (Am. Compl. ¶ 1).

More specifically, SmileDirect is currently subject to: (a) At least 40 state claims filed by the relevant state affiliate of the American Dental Association ("ADA"), American Association of Orthodontists ("AAO"), or similar organizations alleging, in a substantiated fashion, that SmileDirect is illegally operating as a dentist without proper licensing in the subject state. Indeed, a Federal District Court in Georgia recently found that SmileDirect was in fact illegally operating as a dentist in connection with its ordinary course practices. (*Id.* at ¶ 2(a)).

A complaint filed by the ADA with the Federal Trade Commission ("FTC") requesting that the FTC investigate numerous false and misleading claims made by SmileDirect to fraudulently entice customers to purchase its products and services. The ADA's detailed lengthy complaint alleges that SmileDirect has made false and misleading claims and engages in unfair and deceptive practices within the meaning of Section 5 of the Federal Trade Commission Act

("FTCA"), 15 U.S.C. § 45. (*Id.* at ¶ 2(c)).

Rather than address and seek to remedy these substantiated complaints alleging illegal operation, false advertising, and violations of the FTCA and the FD&C Act, SmileDirect instead has taken the low road by (a) refusing to make refunds to customers who have had bona fide problems with the aligners and/or damage relating to their teeth and (b) bringing litigation against ADA or AAO state affiliates and their board members to deflect the claims contained in their state-filed complaints with respect to SmileDirect's illegal operation. (*Id.* at ¶ 3).

A lengthy, detailed and substantiated Citizen Petition filed by the American Dental Association with the federal Food and Drug Administration ("FDA") alleging in a detailed and substantiated fashion that SmileDirect is in continuing violation of the FD&C Act because it is selling plastic aligners that it manufactures in Tennessee (a) without a valid prescription and (b) without having had such aligners approved pursuant to a 510(k) clearance procedure. (*Id.* at $\P 2(b)$).

SmileDirect's omni-channel marketing campaign uses literal falsities and misleading statements, as described herein, and is designed to demean the traditional orthodontic industry, which SmileDirect describes, in its Prospectus, as "competition." Many of those false, misleading, and demeaning statements are contained in the dozens of online commercials compiled by iSpot.tv, including the following:

- Stating that "we can straighten your smile for 60% less than braces;"
- Stating that, "[i]f your aligners aren't a good fit for you, you get your money back;"
- Stating that "you shouldn't have to wear braces to get your smile;"
- Asking "why would anyone go to a dentist's office?;"
- Describing braces as including "embarrassing wires."

These false, misleading, and demeaning statements harm dentists practicing traditional orthodontics and mislead consumers who would otherwise purchase traditional orthodontic services. (Id. at ¶ 77).

In fact, patients do not interact with "treating doctors," either in person, by telephone, or through the SmileDirect internet platform. No doctor is ever identified to the customer as being their treating doctor, and communications between customers and SmileDirect take place through administrative personnel not trained in orthodontics or dentistry. This internet-based administrative interaction is nothing like the seamless communication between a treating doctor and the patient advertised by SmileDirect or employed in traditional orthodontics. Indeed, the SmileDirect "patient" does not even know who the purported dentist is. (*Id.* at ¶ 83).

It is beyond dispute that SmileDirect's version of "teledentistry" is not consistent with the applicable medical standard of care for traditional dentists. Its false marketing injures both consumers and competing dentists. (Id. at ¶ 86).

"Had I had the opportunity to do this over again, I would have coughed up the extra dough and done it the right way with Invisalign. The quality of the tray simply weren't [sic] up to par. I was convinced that they sent me the wrong trays in later months because I wasn't seeing any incremental movement or straightening." (Id. at ¶ 119).

On or about April 25, 2019, the American Dental Association filed a detailed 20-page Citizen Petition with the FDA outlining why SmileDirect's self-manufactured and self-distributed aligner practice violates the FD&C Act. The FDA is currently addressing these issues. On October 10, 2019, the ADA confirmed that "[a]ll substantive issues raised by the ADA's citizen petition remain fully before the FDA at this time." (*Id.* at ¶ 121).

Both of these nondisclosures are highly material and highly fraudulent because consumers would be reluctant to use SmileDirect's aligners in any capacity if they knew that they were being sold in violation of both federal and state law. (*Id.* at ¶ 124).

As a manufacturer of its aligners, SmileDirect was legally obligated to seek FDA clearance for such product, likely pursuant to Rule 510(k). SmileDirect instead has decided to flout these legal requirements and is selling its product, which should be labeled and sold only by prescription, in an essentially over-the-counter fashion. (*Id.* at ¶ 129).

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Against this backdrop, SDC served Align with fifteen document requests that are not only relevant, but that are narrowly-tailored and go directly to issues that are critical to the orthodontists' claims and SDC's defenses in this case. More particularly, these requests are directly relevant to the claims and defenses in the underlying lawsuit for at least fourteen reason:

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First, whether or not the plaintiff orthodontist themselves have benefited from, and SDC harmed by, a coordinated effort by Align, the ADA, and the AAO to disparage SDC and its business model is directly relevant. (**Exhibit A**, Req. Nos. 1, 2 & 9).

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Second, whether SDC at all times had 510(k) clearance and whether it violated any FDA regulation or sold aligners in violation of the Food, Drug & Cosmetic Act is directly relevant. (*Id.* at Req. No. 4).

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Third, whether Align had any involvement whatsoever with complaints made against SDC to various state dental boards by the AAO is directly relevant. (*Id.* at Req. Nos. 6, 7, 8, 9, & 10).

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Fourth, whether SDC's model is safe and whether Align is aware of any clinical or scientific study or research that compares SDC to Align, or that supports or refutes the various statements made by Mr. Hogan and others at Align is directly relevant. (*Id.* at Req. Nos. 13 & 14)

Fifth, whether Align had communications with or otherwise participated in a complaint against SDC to the Federal Trade Commission is directly relevant. (*Id.* at Req. No. 5).

Sixth, whether the plaintiffs or their attorneys have been in communication with the plaintiff orthodontists or their attorneys regarding SDC or the lawsuit is undeniably relevant. (*Id.* at Req. No. 12).

Seventh, whether Align's marketing materials and other communications make representations about SDC or its products or services that either disparaged SDC or benefitted the plaintiff orthodontists and their practices is directly relevant. (*Id.* at Req. No. 11).

Eighth, these documents are relevant to whether the plaintiff orthodontists have been damaged.

Ninth, these documents are relevant to whether the plaintiff orthodontists' association with Align affects their ability to serve as adequate class representatives.

Tenth, these documents are relevant to whether, given Align's statements, SDC's products and services are safe, effective, and/or legal.

Eleventh, these documents are relevant to whether an in-person examination or office visit is necessary to meet the "standard of care," whatever that standard is.

Twelfth, these documents are relevant to whether SDC's products and services are comparable to Align's, which the plaintiff orthodontists sell to their patients.

Thirteenth, whether Align had any involvement whatsoever with the ADA's Citizen Petition to the FDA or communicated it to Align's orthodontist network is directly relevant. (*Id.* at Req. Nos. 9 & 10).

Fourteenth, these documents are relevant to the plaintiff orthodontist's claim (Ex.

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27 28 K, \P 77) that SDC "falsely" advertised that its clear aligners were 60% less expensive than the cost of braces. In fact, Align filed and lost a complaint that it made against SDC with the National Advertising Division ("NAD") that this very claim was untrue. The NAD disagreed and rejected Align's claims. (**Exhibit N**).

In fact, the relevance of SDC's targeted document requests cannot seriously be disputed under the governing law of this Court. This was the finding of this Court in Aquastar Pool Products. Aquastar Pool Prods., 2019 U.S. Dist. LEXIS 8273. In that case, the Petitioner served a Rule 45 subpoena duces tecum on Respondent Paramount Pool & Spa Systems, a nonparty competitor. *Id.* at *1. Petitioner had filed a patent lawsuit against a third company, Color Match Pool Fittings, and sought documents from Petitioner that related to the claims in the case. *Id.* at *1-2. Respondent objected, claiming lack of relevance, undue burden, and insufficient time to respond. *Id.* at *2. The Court disagreed finding that, under a liberal standard of relevance appropriate to documents sought pursuant to the federal rules, Petitioner had adequately demonstrated a need for the materials: "[T]he Court is satisfied the materials sought ... are 'relevant to any party's claim or defense' in the underlying patent litigation 'and proportional to the needs of the case." Id. at *7 (emphasis added). Noting that the defendant in the patent litigation and the Respondent were "closely aligned," it held that the requests were tailored to capture documents that would be relevant to the infringement claims and counterclaims: "The responsive documents are thus likely to discuss such topics as sales and alternative designs—matters at the heart of the underlying litigation." *Id*.

3. Align Cannot Show Undue Burden or Expense

Although SDC was willing to work with counsel for Align to find a principled, meaningful compromise if there was truly a burden or undue expense, Align's counsel made this impossible by not conducting any search for documents prior to serving its objections or prior to engaging in a meet-and-confer. Although it is SDC's position that Align's conduct estopps it from now complaining about undue burden or expense, the practical result is that this Court's mandate for good faith meet-and-confer to avoid

burdening this Court with discovery dispute is rendered moot when one party complains about "burden" without having made any effort at all to actually find out if it has responsive documents, if they are relevant, where the documents are located, how voluminous the documents are, whether they can be collected and produced with minimal effort, what the cost would be, or whether anything is actually privileged. Align did not of these things, but has instead engaged in gamesmanship that should not be tolerated.

IV. CONCLUSION

For all of the foregoing reasons, SDC respectfully requests that this Court:

(1) strike all of Align's objections for violating its duty of good faith in responding to a federal subpoena; (2) order Align to produce all of the requested documents within 30 days at Align's own expense, and (3) award SDC the costs and attorneys' fees incurred in connection with this motion and such other relief as the Court deems just and equitable.

Respectfully submitted,

/s/ Jeremy C. Johnson
Jeremy C. Johnson
JONES, SKELTON & HOCHULI, P.L.C.
40 North Central Avenue
Suite 2700
Phoenix, Arizona 85004
Telephone: (602) 263-4453
Facsimile: (602) 200-7868
jjohnson@jshfirm.com

Counsel for Petitioner SmileDirectClub, Inc.